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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,296

06/01/2006

Sudhir Paul

3694

7590 09/01/2009
Benjamin A. Adler, PhD, JD
8011 Candle Ln.
Houston, TX 77071

EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,296	Applicant(s) PAUL ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-22, 25-28, 30-34, 44-48 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) 25-28, 30-34, 44-48, 64 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-22, 62 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/6/07 (x2)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on May 11, 2009 is acknowledged. Applicant's reply does not specifically elect a single compound for examination on the merits, but rather identifies variables of portions of the compound. Applicant indicates that the L_1 and L_m are "polypeptides" and that m is 1-30, however this is not a single species, but rather defines multiple variables. Applicant has stated clearly on the record that " n is 1, is not patentably distinct from any other n value up to and including the recited n is 1000".

The traversal is on the ground(s) that Applicant argues there is unity of invention and that "ALL of the CAL structures covered by Formula (1) of amended claim 1 share the common feature of covalent binding to NuRs guided by noncovalent binding thereto to elicit an affect on the NuR. This is not found persuasive because, the compounds of Formula (1) share no common core, structure or 'feature', as asserted by Applicant, in that they are "components of the ligand determinant" and it does not constitute a common core necessary for unity of invention.

In light of the indefiniteness and descriptive issues, discussed below, the species election is withdrawn, however, the requirement may be set forth at such time as the claims are rendered clear and definite.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5, 10-22, 25-28, 30-34, 44-48, and new claims 62-65 are pending. Claims 25-28, 30-34, 44-48, 64 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 11, 2009.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: The specification appears to be arranged as chapters in a book/dissertation, with references/citations and footnotes placed periodically throughout the specification. Applicant is suggested to place all of the references at the end of the specification, or submit the references on an IDS. Footnotes will not translate to the publication as they would in a book publication, and thus Applicant is suggested to amend the specification to insert the 'footnotes' within the body text.

Please note, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163 states that, “[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).” Further, the MPEP states, “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

In the instant case, claims 21 and 22 have redefined that the ligand determinant "is a polypeptide comprising", where previously it was, either a linear or non-linear polyamino acid. There is no explicit, implicit or inherent support for this change in concept and scope of the claimed invention. Further, the scope of new claims 62 and 63 are not supported by implicit, inherent or explicit support. In both cases, the claims and specification provide no definition for L₁ and L_m, and thus one cannot conclude that they are peptides, polysaccharides, etc, as in claim 62 or 63. Furthermore, given the absence of a definition, one cannot find support that the "ligand determinant" would be a polypeptide comprising a linear or non-linear polyamino acid.

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Furthermore, Applicant has pointed to no portions of the specification for support for the claim amendments.

Claims 1-5, 10-22, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to be considered in making the determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing include: (a) Actual reduction to practice; (b) Disclosure of drawings or structural chemical formulas; (c) Sufficient relevant identifying characteristics such as: (i) Complete structure, (ii) Partial structure, (iii) Physical and/or chemical properties or (iv) Functional characteristics when coupled with a known or disclosed correlation between function and structure; (d) Method of making the claimed invention; (e) Level of skill and knowledge in the art and (f) Predictability in the art. While all of these factors are considered, a sufficient number for a *prima facie* case are discussed below.

Here, Applicant has provided few compounds, e.g. figure 18, which are within the scope of the claimed invention. Beyond these compounds, which are so closely related in structure, Applicant has provided no description of compounds which are within the metes and bounds of the claims that would function as claimed- a covalently active ligand analog. The claims lack a description of L_1 and L_m , being defined as "components defining a ligand determinant" and L_x is "a component unit of the ligand determinant". Such description provides no complete or partial

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structure such that one would recognize the compounds envisaged by the claims. Furthermore, while synthesis of peptides are known to the artisan, synthesis of compounds with the requisite function is beyond the skill of the artisan, as one does not know the function required (“covalently active ligand analog”) or what structure is required to impart such function, nor does the specification provide guidance as to how one would identify the required structure.

Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-5, 10-22, 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: definitions of L_1 and L_m . Applicant has defined the group of elements $L_1...L_x...L_m$ as "components defining a ligand determinant", where L_x is defined in a dependent claim as an amino acid, however L_1 and L_m are not defined in the claims.

Furthermore, it is unclear what is "a ligand determinant", as the claims and specification provides no definition. Additionally, it is unclear what is "a component of a ligand determinant".

Claim Rejections - 35 USC § 102

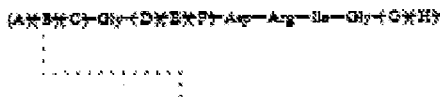
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 13, 18, 19, 21, 22, 62 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by TANAKA (US 5,434,133).



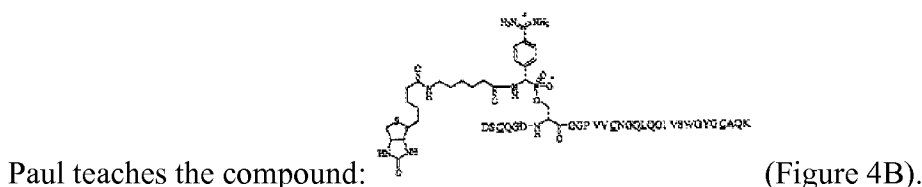
Tanaka teaches the compound: Ser-Gly-Leu-Gly-Ser (e.g. Abstract).

The peptide portion with Ser-Gly-Leu-Gly broadly reads upon the functionalities Y'' , Y' and Y , with the Cys of the A-B moiety being the 'functional group' of L' and L_x , and the remainder of the compound satisfying the requirements of the 'ligand determinant'.

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Claims 1-5, 13, 18, 19, 21, 22, 62 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by PAUL (US 6,855,804 B2).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.



Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

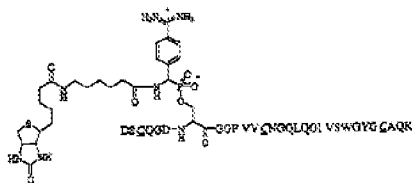
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-5, 10-22, 62 and 63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 10/581,294. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of '294 makes the compounds of the instant claims, and thus the final product of the synthesis of '294 is the claimed product of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

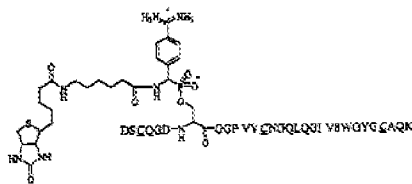
Claims 1-5, 10-22, 62 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,524,663 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds used in '663 anticipate the instant claims. In looking to the specification of '663 for the compounds used in support of the methods, one finds the compound:



Claims 1-5, 13, 18, 19, 21, 22, 62 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. US 6,885,804 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the covalently reactive transition state antigen analogs of '804 anticipate

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the instant CAL, sharing the same structure, with one species of '804 being:



Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654